

-Remarks-

Amendments.

Applicants respectfully request entry of the above amendments and reconsideration and withdrawal of the rejection of Claims 165 and 166. Claim 165 has been amended to limit the definition of  $R^3$  to  $R^{3a}$  and to remove the definitions of all variables no longer required. This claim has been amended without waiver or prejudice to further prosecution. Applicants reserve the right to file divisional or continuation applications directed to the canceled subject matter of this application.

The 35 U.S.C. §112, first paragraph rejection.

The Examiner has rejected Claim 165 under 35 U.S.C. §112, second paragraph, as being indefinite in that it allegedly fails to point out what is included or excluded by the claim language. The Examiner has referred to Claim 165 as an omnibus claim.

Applicants respectfully disagree with the characterization of Claim 165 by the Examiner as an omnibus claim, since every variable is specifically defined in the claim. However, in the interest of expedited prosecution, Applicants have amended Claim 165 so that the definition of  $R^3$  is limited to  $R^{3a}$ . Further, the definitions of Ar and  $Ar^1$  have been limited to a list of heterocycles. Applicants respectfully submit that, in view of the limitations placed upon the definitions of variables  $R^3$ , Ar and  $Ar^1$ , that Claim 165 is definite.

Applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. §112, second paragraph rejection of Claim 165, as amended.

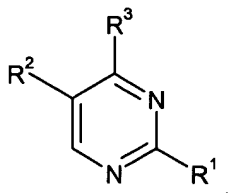
The Double Patenting Rejection.

The Examiner has rejected Claim 165 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1 of U.S. Patent No. 6,414,149 and over U.S. Patent No. 6,602,875. The Examiner has stated that the claims are not patentably distinct, though not identical, because the '149 patent and the '875 patent each recite compounds of formula I wherein the definitions of various components overlap with instant Claim 165. The Examiner has alleged that allowance of Claim 165 would extend the monopoly of US 6,414,149 and US 6,602,875. Applicants respectfully traverse.

Applicants respectfully submit that the standard for obviousness is not whether "definitions of various components [found in the art] overlap" with instant claims. The standard is whether an improvement would have been obvious to a person of ordinary skill in the art. It is possible for an improvement to be no more than a single change. In fact, in the instant application, the definition of the variable  $R^1$  is the only change made over the claims made in the '149 patent and the '875 patent. However, the change is significant in that it renders the instant claims patentably distinct over the claims in the '149 patent and the '875 patent.

a. The '149 patent.

Claim 165 of the instant application is patentably distinct from Claim 1 of the '149 patent as follows. Both the '149 patent and instant Claim 165 are directed to compounds having the formula



In Claim 1 of the '149 patent and Claim 165 of the instant application, the variables  $R^2$  and  $R^3$ , after amendment hereinabove, are the same or virtually the same. However, in the '149 patent,

R<sup>1</sup> is limited to -C(OH)R<sup>4</sup>R<sup>5</sup>, where R<sup>4</sup> and R<sup>5</sup> are either hydrogen or methyl, e.g., R<sup>1</sup> is -CH<sub>2</sub>(OH), -CH(OH)CH<sub>3</sub>, or -C(OH)(CH<sub>3</sub>)<sub>2</sub>. Thus, the definition of R<sup>1</sup> is limited to only three possible radicals. Importantly, a hydroxyl group is required at the carbon atom alpha to the pyrimidine ring.

In instant Claim 165, R<sup>1</sup> is C-(OR<sup>80</sup>)R<sup>4</sup>R<sup>5</sup>, where R<sup>80</sup> is independently (C<sub>1</sub>-C<sub>4</sub>)alkyl, benzyl, (C<sub>1</sub>-C<sub>6</sub>)alkylcarbonyl or phenylcarbonyl, where said benzyl and said phenyl are optionally substituted with up to three (C<sub>1</sub>-C<sub>4</sub>)alkyl, (C<sub>1</sub>-C<sub>4</sub>)alkoxy, halo or nitro. R<sup>4</sup> and R<sup>5</sup> are each independently hydrogen, methyl, ethyl or hydroxy-(C<sub>1</sub>-C<sub>3</sub>)alkyl. None of the three radicals asserted in Claim 1 of the '149 patent are within the scope of R<sup>1</sup> as defined in the instant application. Importantly, the hydroxyl portion is not present in instant Claim 165. Rather, the hydroxyl portion is replaced by an ether or ester moiety, e.g., OR<sup>80</sup>, where R<sup>80</sup> is alkyl, benzyl, alkylcarbonyl or phenyl carbonyl, where each of those groups is optionally substituted.

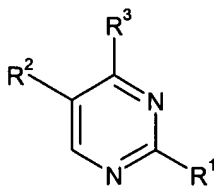
The standard of obviousness, whether under 35 U.S.C. §103 or under obviousness-type double patenting, is whether a person of ordinary skill in the art would be motivated by the reference to arrive at the claimed invention. Applicants submit that nothing in Claim 1 of the '149 patent would motivate a person of ordinary skill in the art to prepare the ether and ester compounds asserted in Claim 165 of the instant invention.

Applicants further respectfully submit that allowance of Claim 165, as amended, would not extend the monopoly of U.S. Patent Nos. 6,414,149 since the compounds within the scope of Claim 165 of the instant application are not within the scope of the '149 patent and are patentably distinct therefrom.

Applicants respectfully request that the Examiner reconsider and withdraw the obviousness-type double patenting rejection of Claim 165 over Claim 1 of the '149 patent.

b. The '875 patent.

Claim 165 of the instant application is patentably distinct from Claim 1 of the '875 patent as follows. Both the '875 patent and instant Claim 165 are directed to compounds having the formula



In Claim 1 of the '875 patent and Claim 165 of the instant application, the variable R<sup>2</sup> is the same or virtually the same. However, in the '875 patent, R<sup>3</sup> must be a bicyclic moiety whereas in Claim 165 of the instant application, R<sup>3</sup>, after amendment, must be a piperazinyl moiety. Further, in the '875 patent, R<sup>1</sup> is limited to formyl, acetyl, propionyl, carbamoyl or -C(OH)R<sup>4</sup>R<sup>5</sup>, where R<sup>4</sup> and R<sup>5</sup> are each independently hydrogen, methyl, ethyl or hydroxy-(C<sub>1</sub>-C<sub>3</sub>)alkyl. Thus, the definition of R<sup>1</sup> is extremely limited and may not have a radical having an ether radical or an ester radical attached to the carbon atom alpha to the pyrimidine ring.

In instant Claim 165, R<sup>1</sup> is C-(OR<sup>80</sup>)R<sup>4</sup>R<sup>5</sup>, where R<sup>80</sup> is independently (C<sub>1</sub>-C<sub>4</sub>)alkyl, benzyl, (C<sub>1</sub>-C<sub>6</sub>)alkylcarbonyl or phenylcarbonyl, where said benzyl and said phenyl are optionally substituted with up to three (C<sub>1</sub>-C<sub>4</sub>)alkyl, (C<sub>1</sub>-C<sub>4</sub>)alkoxy, halo or nitro. R<sup>4</sup> and R<sup>5</sup> are each independently hydrogen, methyl, ethyl or hydroxy-(C<sub>1</sub>-C<sub>3</sub>)alkyl. None of the substituents asserted in Claim 1 of the '875 patent are within the scope of R<sup>1</sup> as defined in the instant application. Importantly, the hydroxyl portion present in the -C(OH)R<sup>4</sup>R<sup>5</sup> radical of the '875 patent is replaced by an ether or ester moiety, e.g., OR<sup>80</sup>, where R<sup>80</sup> is alkyl, benzyl, alkylcarbonyl or phenyl carbonyl, where each of those groups is optionally substituted, in the instant application. Further, there is no provision in Claim 165 of the instant application for R<sup>1</sup> to be formyl, acetyl, propionyl or carbonyl. Further

still, the instant application is limited to piperazine compounds and does not include the bicyclic compounds of Claim 1 of the '875 patent. Thus, there are two patentable distinctions between the instant claims and the claims of the '875 patent.

The standard of obviousness, whether under 35 U.S.C. §103 or under obviousness-type double patenting, is whether a person of ordinary skill in the art would be motivated by the reference to arrive at the claimed invention. Applicants submit that nothing in Claim 1 of the '875 patent would motivate a person of ordinary skill in the art to prepare the ether and ester compounds asserted in Claim 165 of the instant invention.

Applicants further respectfully submit that allowance of Claim 165, as amended, would not extend the monopoly of U.S. Patent Nos. 6,602,875 since the compounds within the scope of Claim 165 of the instant application are not within the scope of the '875 patent and are patentably distinct therefrom.

Applicants respectfully request that the Examiner reconsider and withdraw the obviousness-type double patenting rejection of Claim 165 over Claim 1 of the '875 patent.

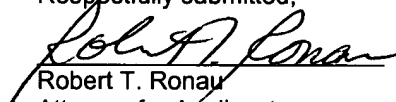
-Conclusion-

Applicants, having responded to all points and concerns raised by the Examiner, believe that this application is in condition for allowance. An early and favorable action is respectfully requested.

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Pfizer Inc.  
Patent Department  
Eastern Point Road  
Groton, CT 06340  
(860) 441-5910

Respectfully submitted,

  
Robert T. Ronau  
Attorney for Applicants  
Reg. No. 36,257